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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,674	08/26/2006	Julia Adam-Worrall	2004.831US	2842
67706 7590 10/09/2008 ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033				
EXAMINER LOEWE, SUN JAE Y				
ART UNIT 1626		PAPER NUMBER		
NOTIFICATION DATE 10/09/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jill.corcoran@spcorp.com
patents@spcorp.com
nancy.joyce.simmons@spcorp.com

Office Action Summary

Application No.

10/590,674

Applicant(s)

ADAM-WORRALL ET AL.

Examiner

SUN JAE Y. LOEWE

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 12 is/are rejected.
- 7) ☒ Claim(s) 6 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-6, 8 and 10-15 are pending in the instant application. Claims 10, 11, 14 and 15 remain withdrawn.

Response to Amendment

2. The amendments to the claimed filed on July 11, 2008 have been fully considered. The following grounds of objection/rejection have been obviated and are thus hereby withdrawn: a) objection to claim 6 (Section 8); b) objection to claim 1 (Section 9); c) 35 USC 112 2nd paragraph rejection (Section 12).

Note: Section numbers refer to those from the office action dated January 11, 2008.

3. The following grounds of rejection are maintained: a) 35 USC 112 1st paragraph (written description and enablement); b) obviousness-type double patenting. Below are responses to Applicant's remarks.

Maintained Claim Objections

4. Claims 1-6, 8, 12 and 13 remain objected to for containing non-elected subject matter. The non-elected subject matter consists of compounds of Formula I that are not the elected species. Pursuant MPEP 803.02, Applicant will be entitled to rejoinder and consideration of non-elected species upon allowability of the generic claims.

Maintained Claim Rejections - 35 USC § 112 1st Paragraph

5. Below are responses to Applicant's remarks:

- a) “ In this regard, more than forty examples of compounds have been disclosed as well as

disclosure of *in vitro* and *in vivo* activity of these compounds as CB1 receptor agonists.

.....

Further, with respect to the Examiner's reference to Tarzia et al. and Huffman et al. to show the unpredictability of the claimed compounds, as acknowledged by the Examiner the structures of the claimed compounds are completely different from the compounds described in the Tarzia et al. and Huffman et al. references, and thus these references say nothing about the predictability of activity with respect to the presently claimed compounds. ”

It is maintained that the forty examples support

R³: H, (C₁₋₆)alkyl;
R⁶: H, (C₁₋₆)alkyl or
R³ and R⁶ form pyrrolidine or morpholine

R⁵/R^{5'}: H or (C₁₋₆)alkyl;
R⁶: H, (C₁₋₆)alkyl.

as set forth in the previous office action (dated January 11, 2008), with the modifications denoted in the subsections below. It is noted that “alkyl” refers to substituted or unsubstituted.

Applicant is respectfully referred to MPEP 2163.II.A.3.(a).ii), excerpts below

ii) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004) ("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed."

Applicant's field of endeavor is unpredictable, and the disclosure of the species does not apprise one of ordinary skill that the unsupported yet claimed compounds (eg, C3-C7 cycloalkyl for R3/R4) would have the same activity. Thus, evidence indicates ordinary artisans could not predict the operability in the invention of any species other than those disclosed (ie. see above).

- b) Considering Applicant's remarks, the following addition is made to the scope

of the disclosure

R3/R4 is piperidine or thiomorpholine
R6 is H or (C1-4)alkyl, such as (C1-4)alkyloxy, halogen or CN

It is maintained that the 35 USC 112 1st paragraph rejection was proper. This ground of rejection is maintained and hereby made FINAL. Claims 1-5, 8 and 12 remain rejected.

Double Patenting

6. Applicant's remarks are noted. The obviousness-type double patenting rejection is currently maintained.

Conclusion

7. No claims allowed.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./
9-23-2008

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626